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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 992,132	11 15 2001	William K. Summers	30011-UT	4628

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,132

Applicant(s)

SUMMERS, WILLIAM K.

Examiner

Susan Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

- A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-35 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-8,15-20 and 22-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,9,11-14,21,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed April 1, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claim 10 has been cancelled.
3. Claims 34 and 35 have been added.
4. Claims 1-9 and 11-35 are currently pending.
5. In Paper No. 6, dated November 25, 2002, applicants elected phosphatidyl choline for species A and the composition of claim 13 for species B. This election was made without traverse.
6. Claims 3, 6-8, 15-20 and 22-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.
7. Claims 1, 2, 4, 5, 9, 11-14, 21, 34, and 35 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite because the claims state that ingredients can be present at zero mg. Then the claims state that there must be at least 500 mg of a component. However, if only one component is required by the composition, how can there be

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both zero and 500 mg? In addition, the upper limitations on the amounts of some of the ingredients does not even reach 500 mg. The conflict in the amounts required is very confusing and makes the actual amounts required unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 9, 11, 12, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,747,773.

US '773 teaches a composition comprising phosphatidyl choline and an antioxidant (see claims 1 and 2). The antioxidant is specified as tocopherols (Vitamin E) (see column 36-38). The phosphatidyl choline is present in amounts from 10 to 30 percent of the composition. The composition is administered in amounts from 1 to 20 grams (see claim 21). Administration of 10 to 30 percent of 1 to 20 grams encompasses the amounts claimed by applicant.

Claim Rejections - 35 USC § 103

8. Claims 1, 2, 4, 5, 9, 11-14, 21, 34, and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,043,323 in view of US Pat. No. 4,474,773.

Applicant has traversed the previous 102 rejection based on US '323. Applicant states that US '323 does not teach the stated claims because the reference does not teach using

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phosphatidyl choline in the amounts claimed. However, US '773 teaches using the claimed amounts of phosphatidyl choline to treat the same diseases that are discussed in US '323. Therefore, a person of ordinary skill in the art would reasonably expect that the amount of phosphatidyl choline in US '323 could be increased to the levels used in US '773 and would be motivated to make these changes based on the fact that both references treat the same disorders.

In addition, applicant has argued that US '323 does not teach that the composition has the same effects as those claimed by applicant. However, applicant's claims are directed towards composition not methods of use. The combination of US '323 and US '773 is considered to teach a composition that is the same as the claimed composition. Therefore, since the compositions are the same, any biological effects would be the same.

9. Claims 1, 2, 4, 5, 9, 11-14, 21, 34, and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,648,377 in view of US Pat. No. 4,474,773.

Applicant has traversed the previous 102 rejection based on US '377. Applicant states that US '377 does not teach the stated claims because the reference does not teach using phosphatidyl choline in the amounts claimed. However, US '773 teaches using the claimed amounts of phosphatidyl choline to treat the same diseases that are discussed in US '377. Therefore, a person of ordinary skill in the art would reasonably expect that the amount of phosphatidyl choline in US '377 could be increased to the levels used in US '773 and would be motivated to make these changes based on the fact that both references treat the same disorders.

In addition, applicant has argued that US '377 does not teach that the composition has the same effects as those claimed by applicant. However, applicant's claims are directed towards composition not methods of use. The combination of US '377 and US '773 is considered to

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teach a composition that is the same as the claimed composition. Therefore, since the compositions are the same, any biological effects would be the same.

10. Claims 1, 2, 4, 5, 9, 11-14, 21, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,043,323, US Pat. No. 5,648,377, and Castleman (*The Healing Herbs* (1991), Rodale Press: Pennsylvania; Barberry, pp. 59-61; Ginseng, pp. 193-200; Gotu Kola, pp. 205-208; and Turmeric, pp. 355-357) in view of US Pat. No. 4,474,773.

Applicant has traversed the previous 103 rejection based on the combination of US '323, US '377, and Castleman. Applicant states that US '323, US '377, and Castleman do not teach the stated claims because the references do not teach using phosphatidyl choline in the amounts claimed. However, US '773 teaches using the claimed amounts of phosphatidyl choline to treat the same diseases that are discussed in the references. Therefore, a person of ordinary skill in the art would reasonably expect that the amount of phosphatidyl choline in US '377 and US '323 could be increased to the levels used in US '773 and would be motivated to make these changes based on the fact that both references treat the same disorders.

In addition, applicant has argued that the references do not teach that the composition has the same effects as those claimed by applicant. However, applicant's claims are directed towards composition not methods of use. The combination of the references is considered to teach a composition that is the same as the claimed composition. Therefore, since the compositions are the same, any biological effects would be the same.

11. No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
June 12, 2003


LEON B. LANKFORD, JR.
PRIMARY EXAMINER